

THAT WHICH IS CLAIMED IS:

1. A hyperpolarized gas delivery system comprising:
 - 5 an enclosed gas flow path having a plurality of spaced apart individually operable valves positioned in fluid communication therewith located along the gas flow path, wherein the gas flow path intermediate the spaced apart valves define at least one meted holding space with an associated volume that can be selectively isolated from the remainder of the gas flow path;
 - 10 a pressure sensor operably associated with the gas flow path; and
 - 15 a control module operably associated with the plurality of spaced apart valves and the pressure sensor, the control module being configured to direct the operational sequence of the opening and closing of the valves, wherein, in operation, the control module directs a plurality of capture and release cycles, the cycles being successively carried out so to temporally isolate a predetermined portion of the gas flow path to capture and then release discrete amounts of gas, including hyperpolarized gas, therein.
2. A system according to Claim 1, wherein the control module is configured to sequentially close a downstream valve, open an upstream valve, then close the upstream valve to close the meted space to capture a discrete amount of gas in the meted space, and is further configured to subsequently open the downstream valve while the upstream valve is closed to release the discrete amount of gas captured in the meted space so that the discrete amount of gas travels in a predetermined direction downstream of the meted space.
- 25 3. A system according to Claim 2, wherein the control module is configured to repeat the operational opening and closing of selected valves rapidly to dispense a cumulative aliquot of the serial discrete amounts of captured and released gas.
- 30 4. A system according to Claim 3, wherein the control module is configured so that the repeated operational sequence is carried out in less than about 30 seconds to dispense an aliquot amount of gas.

5. A system according to Claim 1, wherein the at least one meted space comprises two meted spaces, each having a different associated volume, and wherein, during operation, each meted space is automatically selected to carry out the capture and release cycle by the control module.
- 10 6. A system according to Claim 5, wherein the two meted spaces include first and second meted spaces, the first meted space having a fine adjustment volume and the second having coarse adjustment volume that is larger than the first fine adjustment volume.
- 15 7. A system according to Claim 1, wherein the control module comprises computer program code that receives pressure data from the pressure sensor proximate in time to the initiation of the first capture and release cycle and determines the number of capture and release cycles needed to provide a desired cumulative dispensed amount of gas.
- 20 8. A system according to Claim 7, wherein the control module comprises computer program code that receives pressure data from the pressure sensor and determines the number of capture and release cycles needed from each of the first and second spaces to provide a desired cumulative or aliquot dispensed amount of gas.
- 25 9. A system according to Claim 7, wherein, for each bolus or aliquot of target gas desired to be dispensed, the control module automatically rapidly serially directs the determined number of the capture and release cycles based on a single pressure measurement input proximate and prior to initiation of the first capture and release cycle.
- 30 10. A system according to Claim 7, wherein the gas is a hyperpolarized gas, and wherein the control module further comprises computer program code for automatically determining *in situ*, the amount of hyperpolarized gas to be dispensed for a bolus based on input about at least one of: (a) the polarization level of the hyperpolarized gas to be dispensed; (b) the type of hyperpolarized

gas being dispensed; (c) the desired cumulative bolus size; and (d) the desired polarization percentage in the final dispensed polarized gas blend.

11. A system according to Claim 10, wherein the control module comprises
5 computer program code for automatically dynamically adjusting *in situ* the amount of hyperpolarized gas to be dispensed between successive boluses of dispensed target gas.
12. A system according to Claim 1, wherein the control module comprises
10 computer program code that receives pressure data from the pressure sensor proximate in time to the initiation of the first capture and release cycle for each different bolus dispensed and determines for each bolus the number of capture and release cycles needed from the at least one meted space to provide a desired cumulative dispensed amount of gas.
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13. A system according to Claim 1, wherein, for each bolus, the system is configured to serially dispense a first hyperpolarized noble gas and a second non-polarized noble gas into the gas flow path, and wherein the control module is configured to dispense the non-polarized gas from the system and through the meted space prior to the hyperpolarized noble gas.
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14. A system according to Claim 13, wherein the control module comprises
computer program code that receives pressure data from the pressure sensor proximate in time to the initiation of the first capture and release cycle for dispensing the non-polarized gas and then again proximate in time to the first capture and release cycle for dispensing the hyperpolarized gas and individually determines the number of capture and release cycles needed for each of the non-polarized and the hyperpolarized gas to provide a desired cumulative formulation blend of dispensed gases.
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15. A system according to Claim 14, wherein the control module further comprises
30 computer program code for automatically determining *in situ* the amount of hyperpolarized gas and non-polarized gas to be dispensed for each bolus based on input about at least one of: (a) the polarization level of the hyperpolarized

gas to be dispensed; (b) the type of hyperpolarized gas being dispensed; (c) the desired bolus size; and (d) the desired polarization percentage in the final dispensed formulated polarized gas blend.

- 5 16. A system according to Claim 15, wherein the control module comprises computer program code for automatically dynamically adjusting *in situ* the amount of hyperpolarized gas and non-polarized gas dispensed between each successive bolus.
- 10 17. A system according to Claim 14, wherein the control module comprises computer program code that determines, for each bolus, the number of capture and release cycles needed from the first and second meted spaces for the hyperpolarized gas and the non-polarized gas to provide a desired cumulative dispensed gas blend formulation.
- 15 18. A system according to Claim 1, further comprising an enclosed gas receptacle positioned in the gas flow path downstream of the meted space.
- 20 19. A system according to Claim 18, wherein the system is adapted to dispense into gas receptacles having different sizes, and wherein the control module comprises computer program product for allowing user input to identify the size of the gas receptacle.
- 25 20. A system according to Claim 1, further comprising:
 a vacuum pump in fluid communication with the gas flow path; and
 a purge gas source in fluid communication with the gas flow path,
wherein, the control module comprises computer program code for automatically controlling the valves and directing the vacuum pump and purge gas to purge and evacuate the gas flow path in advance of the first capture and release cycle.
- 30 21. A system according to Claim 18, further comprising a hyperpolarized gas source and a buffer gas source in selectable fluid communication with the gas flow path.

22. A system according to Claim 21, wherein the hyperpolarized gas source is an optical pumping cell that is positioned on a first end portion of the gas flow path upstream of the gas receptacle.
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23. A system according to Claim 22, wherein the buffer gas source is a pressurized nitrogen gas cylinder.
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24. A system according to Claim 22, wherein in operation, the hyperpolarized gas, a non-polarized target gas mixture configured to be optically pumped through spin-exchange, and the buffer gas flow controllably through the gas flow path at different times.
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25. A system according to Claim 24, wherein the plurality of valves are configured to direct the non-polarized target gas mixture into the optical pumping cell and then, after hyperpolarization via spin-exchange, to initiate the capture and release dispensing cycles.
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26. A hyperpolarized gas production system, comprising:
- an optical pumping cell configured for hyperpolarizing gas via spin-exchange with an optically pumped alkali metal, the optical pumping cell having an associated port and a known volume, wherein, in operation, the optical pumping cell has an associated pressure of above about 1 atm;
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- an enclosed gas flow path extending between the pressurized pumping cell and a dispensing outlet port, the gas flow path having at least first, second, and third spaced apart individually operable valves positioned in fluid communication therewith and located along the gas flow path, the first valve located upstream of the second valve closer to the optical pumping cell, wherein the gas flow path located intermediate the first, second, and third spaced apart valves define a first meted holding space with an associated volume that can be selectively closed off from the remainder of the gas flow path, the gas flow path, the dispensing port being located downstream of the first meted space;
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- a pressure sensor operably associated with the gas flow path; and

- a control module operably associated with the first, second, and third spaced apart valves and the pressure sensor, the control module being configured to automatically direct the operational sequence of the opening and closing of the first, second, and third valves, wherein, in operation, the control module directs a plurality of hyperpolarized gas capture and release cycles, with the third valve closed, the control module sequentially closes the second valve, opens the first valve, and then closes the first valve to close the meted space from the remainder of the gas flow path to capture a discrete amount of hyperpolarized gas in the first meted space, then the control module subsequently opens the second valve while the first valve is closed to release the discrete amount of hyperpolarized gas captured in the first meted space so that the discrete amount of hyperpolarized gas travels to the dispensing port.
27. A system according to Claim 26, further comprising fourth, fifth and sixth valves operably associated with the gas flow path, wherein the portion of the gas flow path located intermediate of the first, second, fourth, fifth and sixth valves define a second meted space that is selectively able to be sealed from the remainder of the gas flow path, the second meted space having a volume that is greater than the first meted space.
28. A system according to Claim 27, wherein, in operation, the control module directs a plurality of hyperpolarized capture and release cycles using the second meted space, so that, with the fourth, fifth and sixth valves closed and the third valve open, the control module sequentially closes the second valve, opens the first valve, and then closes the first valve to close the second meted space from the remainder of the gas flow path to capture a discrete amount of gas in the second meted space, and then the control module subsequently opens the second valve while the first valve is closed to release the discrete amount of gas captured in the second meted space so that the discrete amount of gas travels to the dispensing port.
29. A system according to Claim 28, wherein, in operation, the control module is configured to automatically adjust the operation of the valves to cause the gas to

selectively travel in a desired one of the first or second meted spaces during the capture and release cycle.

30. A system according to Claim 26, wherein the gas flow path is in fluid communication with a source of pressurized non-polarized medical grade buffer gas, and wherein the control module directs the operational sequence of the opening and closing of the first, second, and third valves to dispense an aliquot of the buffer gas out the dispensing port in advance of the aliquot of hyperpolarized gas for each bolus.
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10. A system according to Claim 30, wherein, in operation, the control module directs a plurality of buffer gas capture and release cycles, with the first valve closed, the control module sequentially closes the second valve, opens the third valve, then closes the third valve to close the first meted space from the remainder of the gas flow path to capture a discrete amount of buffer gas in the meted space, and then the control module subsequently opens the second valve while the first and third valves are closed to release the discrete amount of buffer gas captured in the first meted space so that the discrete amount of buffer gas travels to the dispensing port.
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20. A system according to Claim 26, further comprising fourth, fifth and sixth valves operably associated with the gas flow path, wherein the portion of the gas flow path located intermediate of the first, second, fourth, fifth and sixth valves define a second meted space that is selectively able to be closed off from the remainder of the gas flow path, the second meted space having a volume that is greater than the first meted space.
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30. A system according to Claim 32, wherein, in operation, the control module directs a plurality of buffer capture and release cycles using the second meted space, so that, with the first, fourth, and fifth valves closed and the third valve open, the control module sequentially closes the second valve, opens the sixth valve, and then closes the sixth valve to close the second meted space from the remainder of the gas flow path to capture a discrete amount of gas in the second meted space, and then the control module subsequently opens the second valve

while the sixth valve is closed to release the discrete amount of gas captured in the second meted space so that the discrete amount of gas travels to the dispensing port

- 5 34. A system according to Claim 26, wherein the pressure sensor is located outside the first meted region of the gas flow path.
- 10 35. A system according to Claim 26, wherein, in operation, during a plurality of the hyperpolarized gas capture and release cycles, the pressure in the optical pumping cell decreases.
- 15 36. A system according to Claim 33, wherein the pressure downstream of the first and second meted regions in the gas flow path remains substantially constant during the buffer gas capture and release cycles.
- 20 37. A system according to Claim 26, further comprising a gas receiving container operably associated with the gas dispensing port, wherein the system is configured to dispense gas to a plurality of different container types and/or sizes.
- 25 38. A system according to Claim 26, wherein the control module comprises computer program code that receives pressure data from the pressure sensor proximate in time to the initiation of the first hyperpolarized gas and buffer capture and release cycles and determines the number of hyperpolarized gas and buffer capture and release cycles needed to provide a desired cumulative dispensed formulation amount of gas mixture.
- 30 39. A system according to Claim 28, wherein the control module comprises computer program code that receives pressure data from the pressure sensor and determines the number of hyperpolarized gas capture and release cycles needed from each of the first and second meted spaces to provide a desired cumulative or aliquot dispensed amount of hyperpolarized gas.

40. A system according to Claim 26, wherein, for each bolus or aliquot of hyperpolarized or buffer gas desired to be dispensed, the control module automatically rapidly serially directs the determined number of the capture and release cycles based on a single pressure measurement input proximate and prior to initiation of the first capture and release cycle for each of the hyperpolarized gas and buffer gas, and wherein the buffer gas is dispensed prior to the hyperpolarized gas.
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41. A system according to Claim 26, wherein the control module further comprises computer program code for automatically determining *in situ*, the amount of hyperpolarized gas to be dispensed for a bolus based on input about at least one of: (a) the polarization level of the hyperpolarized gas to be dispensed; (b) the type of gas being dispensed; (c) the desired cumulative bolus size; and (d) the desired polarization percentage in the final dispensed polarized gas blend.
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42. A system according to Claim 40, wherein the control module comprises computer program code for automatically dynamically adjusting *in situ* the amount of hyperpolarized gas to be dispensed between successive patient-sized boluses of dispensed hyperpolarized gas.
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43. A system according to Claim 26, wherein the control module comprises computer program code that receives pressure data from the pressure sensor temporally proximate in time to the initiation of the first hyperpolarized gas capture and release cycle for each different bolus dispensed and determines for each bolus the number of hyperpolarized gas capture and release cycles needed from the first meted space to provide a desired cumulative dispensed amount of hyperpolarized gas.
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44. A system according to Claim 30, wherein the control module comprises computer program code that receives pressure data from the pressure sensor proximate in time to the initiation of the first buffer gas capture and release cycle for dispensing the buffer gas and then again proximate in time to the first hyperpolarized gas capture and release cycle for dispensing the hyperpolarized gas and individually determines the number of capture and release cycles
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needed for each of the buffer and the hyperpolarized gas to provide a desired cumulative formulation blend of dispensed gases.

45. A system according to Claim 30, wherein the control module further comprises
5 computer program code for automatically determining, *in situ*, the amount of hyperpolarized gas and buffer gas to be dispensed for each bolus based on input about at least one of: (a) the polarization level of the hyperpolarized gas to be dispensed; (b) the type of hyperpolarized gas being dispensed; (c) the desired bolus size; and (d) the desired polarization percentage in the final dispensed
10 formulated polarized gas blend.
46. A system according to Claim 45, wherein the control module comprises computer program code for automatically dynamically adjusting *in situ* the amount of hyperpolarized gas and buffer gas dispensed between each successive
15 bolus.
47. A system according to Claim 27, wherein the gas flow path is in fluid communication with a source of pressurized non-polarized medical grade buffer gas, and wherein the control module directs the operational sequence of the opening and closing of the first, second, and third valves to dispense an aliquot
20 of the buffer gas out the dispensing port in advance of the aliquot of hyperpolarized gas, and wherein the control module comprises computer program code that determines, for each aliquot, the number of capture and release cycles needed from the first and second meted spaces for the
25 hyperpolarized gas and the buffer gas to provide a desired cumulative dispensed gas blend formulation.
48. A system according to Claim 26, wherein the system is adapted to dispense into gas receptacles having different sizes, and wherein the control module
30 comprises computer program product for allowing user input to identify the size of the gas receptacle.
49. A system according to Claim 26, further comprising:
a vacuum pump in fluid communication with the gas flow path; and

- a purge gas source in fluid communication with the gas flow path; wherein the control module comprises computer program code for automatically controlling the valves and directing the vacuum pump and purge gas to purge and evacuate the gas flow path in advance of the first capture and
- 5 release cycle.
50. A system according to Claim 26, wherein the system is configured to dynamically adjust the amount of dispensed hyperpolarized gas automatically *in situ* to provide a pharmaceutical formulation desired.
- 10 51. A system according to Claim 26, wherein, at initiation of dispensing, the optical pumping cell contains a multi-bolus amount of hyperpolarized gas pressurized to above 1 atm.
- 15 52. A system according to Claim 51, wherein the hyperpolarized gas comprises hyperpolarized ^3He and/or ^{129}Xe .
53. A system according to Claim 51, wherein the hyperpolarized gas comprises at least one of ^{13}C , ^{15}N , or ^{19}F .
- 20 54. A system for dispensing hyperpolarized gas, comprising:
means for evacuating and purging a gas flow path of contaminants;
means for dynamically adjusting *in situ* aliquot amounts of a buffer gas and hyperpolarized gas desired to yield a patient bolus of a pharmaceutical product formulation;
- 25 means for automatically serially rapidly temporarily capturing and releasing discrete amounts of buffer gas to dispense a desired cumulative amount of buffer gas from the gas flow path into a gas dispensing outlet;
means for accumulating the captured and released discrete amounts of buffer gas exiting the dispensing outlet;
- 30 means for serially rapidly temporarily capturing and releasing discrete amounts of hyperpolarized gas to dispense a desired cumulative amount of hyperpolarized gas; and

means for accumulating the captured and released discrete amounts of hyperpolarized gas exiting the dispensing outlet.

55. A method of dispensing hyperpolarized gas formulations, comprising:
 - 5 providing a pressurized hyperpolarized gas source;
 - directing the hyperpolarized gas from the hyperpolarized gas source to travel downstream in a predetermined enclosed gas flow path to an intermediate portion of the gas flow path;
 - capturing and releasing discrete amounts of the hyperpolarized gas
 - 10 sealing in the intermediate portion of the gas flow path, the intermediate portion having a known volume; and
 - directing the discrete amounts of the captured and released hyperpolarized gas to travel downstream from the intermediate portion of the gas flow path to exit a gas dispensing port associated therewith to produce a
 - 15 first bolus of hyperpolarized gas product.
56. A method according to Claim 55, further comprising detecting a first pressure associated with the pressure in the hyperpolarized gas source prior to initiating the capturing and releasing step and determining the number of capturing and releasing cycles needed to dispense a first bolus of hyperpolarized gas.
57. A method according to Claim 56, wherein the hyperpolarized gas source is a multi-bolus sized source, and the method further comprises detecting a second pressure associated with the pressure in the hyperpolarized gas source prior to re-initiating the capturing and releasing step to dispense the second bolus, and determining the second number of capturing and releasing cycles needed to dispense a desired cumulative amount of hyperpolarized gas to output the second bolus amount of hyperpolarized gas.
- 30 58. A method according to Claim 55, further comprising:
 - providing a pressurized buffer gas source;
 - directing the buffer gas from the buffer gas source to travel downstream thereof in the enclosed gas flow path to the intermediate portion of the gas flow path;

- successively selectively temporarily sealing spaced apart portions of the intermediate portion of a gas flow path so that the intermediate portion of the gas flow path is isolated from the remainder of the gas flow path and then rapidly opening the sealed intermediate portion of the gas flow path, the intermediate portion having a known volume; and
- 5 directing the discrete amounts of the captured and released buffer gas to travel downstream from the intermediate portion of the gas flow path to exit a gas dispensing port associated therewith to produce a first bolus of hyperpolarized gas blended product.
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59. A method according to Claim 55, wherein the intermediate portion of the gas flow path is selectively adjustable from a first intermediate space having a first volume to a second intermediate space having a second volume larger than the first volume.
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60. A method according to Claim 58, wherein the intermediate portion of the gas flow path is selectively adjustable from a first intermediate space having a first volume to a second intermediate space having a second volume larger than the first volume.
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61. A method according to Claim 56, wherein the capturing and releasing steps are carried out automatically to dispense a desired quantity of hyperpolarized gas, and wherein the quantity is adjusted dynamically at the time of dispensing based on one or more of: (a) the type of hyperpolarized gas being dispensed; (b) the planned clinical application of the hyperpolarized gas; (c) the polarization level of the gas being dispensed; (d) the percent polarization desired in the product formulation; and (e) the cumulative bolus amount of the hyperpolarized product.
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62. A computer program product for operating a hyperpolarized gas dispensing system having a gas flow path with a plurality of spaced apart remote-controlled actuated valves that open and close to direct the flow of gas therein and to close off at least one intermediate portion of the gas flow path having a known volume, the computer program product comprising:

a computer readable storage medium having computer readable program code embodied in said medium, said computer-readable program code comprising:

- 5 computer readable program code that obtains the pressure of a pressurized hyperpolarized gas source;
- 10 computer readable program code that obtains the polarization level of the hyperpolarized gas held in the hyperpolarized gas source;
- 15 computer readable program code the receives input about the desired formulation of hyperpolarized product, including at least one of: the target bolus volume; the desired bolus polarization level percentage or concentration; the type of gas(es) to be dispensed to form the bolus; and the size and/or type of the bolus container;
- 20 computer readable program code that calculates the amount of hyperpolarized gas needed to produce the desired bolus formulation;
- 25 computer readable program code that calculates the number of capture and release actuations of predetermined ones of the actuated valves needed to dispense the calculated amount; and
- 30 computer readable program code that automatically transmits control signals to the predetermined ones of the remote actuated valves during operation of the dispensing system to cause selected valves to open and/or close at appropriate times so as to selectively temporarily close off a predetermined intermediate portion of the gas flow path having a known volume from the remainder of the gas flow path to capture a discrete amount of gas therein and to then rapidly open to release the captured discrete amount of gas therefrom.
63. A computer program product according to Claim 62, further comprising computer readable program code that dynamically considers, and adjusts as needed, the aliquot amount of hyperpolarized gas needed to produce the desired bolus formulation for each successive dispensed bolus; and
- 30 computer readable program code that re-calculates the number of capture and release actuations of predetermined ones of the actuated valves needed to dispense the calculated aliquot amount of hyperpolarized gas bolus to bolus.

64. A computer program product according to Claim 62, further comprising computer readable program code that determines the amount of buffer gas needed to produce the desired bolus formulation;
- computer readable program code that calculates the number of capture and release actuations of predetermined ones of the actuated valves needed to dispense the calculated amount of the buffer gas; and
- computer readable program code that initiates the actuation of the valves to dispense the buffer gas in advance of the hyperpolarized gas.
- 10 65. A computer program product according to Claim 62, further comprising computer readable program code for using the universal pressure relationship, the volume of the closed intermediate portion of the gas flow path, and the pressure of the pressurized source of hyperpolarized gas and buffer gas to determine the number of actuations and valves needed to dispense the desired aliquot amounts of buffer gas and hyperpolarized gas.
- 15 66. A computer program product according to Claim 62, further comprising computer program code for initiating a purge and evacuation of the gas flow path in advance of the dispensing of the buffer and hyperpolarized gases.
- 20 67. A computer program product for operating a hyperpolarized gas dispensing system having a gas flow path with a plurality of spaced apart remote-controlled actuated valves that open and close to direct the flow of gas therein and to close off at least one intermediate portion of the gas flow path having a known volume, the computer program product comprising:
- a computer readable storage medium having computer readable program code embodied in said medium, said computer-readable program code comprising:
- computer readable program code that automatically transmits control signals to predetermined ones of the remote actuated valves during operation of the dispensing system to cause selected valves to open and/or close at appropriate times so as to selectively temporarily close off at least one predetermined intermediate portion of the gas flow path having a known volume from the remainder of the gas flow path to capture a discrete amount of

hyperpolarized gas or buffer gas therein and to then rapidly open to release the captured discrete amount of hyperpolarized gas or buffer gas therefrom.

68. A computer program product according to Claim 67, wherein the at least one predetermined intermediate portion comprises individually selectable first and second intermediate portions having different first and second associated volumes, respectively, the computer program product further comprising computer readable program code that automatically determines and selects the appropriate combination of the first and second intermediate portions to output the desired aliquot amounts of buffer and hyperpolarized gas.
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69. A computer program product according to Claim 68, further comprising computer program code that dynamically calculates, and adjusts as needed, the aliquot amount of hyperpolarized gas needed to produce the desired bolus formulation for each successive dispensed bolus; and
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15 computer readable program code that re-calculates the number of capture and release actuations of valves needed to dispense the calculated aliquot amount of hyperpolarized gas bolus to bolus.
70. A computer program product for operating a hyperpolarized gas dispensing system having a gas flow path with a plurality of spaced apart remote-controlled actuated valves that open and close to direct the flow of gas therein and to close off at least one intermediate portion of the gas flow path having a known volume, the computer program product comprising:
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25 a computer readable storage medium having computer readable program code embodied in said medium, said computer-readable program code comprising:
30 a capture and release cycle calculation module that calculates the number of valve actuation cycles needed to output a desired aliquot of polarized gas.
71. A computer program product according to Claim 70, further comprising computer program code that obtains data corresponding to the polarization level of a hyperpolarized gas source; and computer program code that obtains data

corresponding to the pressure of a portion of the gas flow path, and wherein the capture and release calculation module considers the polarization and pressure data to determine the number of capture and release cycles.

- 5 72. A computer program product according to Claim 71, wherein the capture and release cycle calculation module selects the number of cycles to successively isolate one or more of a fine meted space and/or a coarse meted space in the gas flow path to yield the desired aliquot amount of gas being dispensed.
- 10 73. A computer program product according to Claim 71, wherein the capture and release cycle calculation module selects the number of cycles used to successively isolate one or more of a fine meted space and/or a coarse meted space in the gas flow path to yield the desired aliquot amount of both a non-polarized filler gas and the hyperpolarized gas.